UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	MASTER FILE 1:06-MD-1789 (JFK)
This document relates to: Judith Graves v. Merck & Co., Inc., No. 1:06-cv-05513 (JFK)	**OPINION & ORDER**

APPEARANCES:

FOR THE PLAINTIFF, JUDITH GRAVES:

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JOHN F. KEENAN, United States District Judge:

This is one of the "bellwether" cases selected for trial as part of the In re Fosamax Products Liability Litigation multidistrict litigation ("Fosamax MDL"). This opinion addresses Defendant Merck & Co. Inc.'s ("Merck") motions to exclude testimony under Daubert v. Merrell Dow Pharms., 509 U.S. 579(1993), and for summary judgment against Plaintiff Judith Graves ("Graves"). For the reasons discussed below, Merck's

motion for the exclusion of expert witness testimony on Daubert grounds is granted with respect to Drs. Richard Adams, John Akers, and Robert Marx, but denied with respect to Drs. Douglas Villaret and James Cherry. Furthermore, Merck's motion for summary judgment is denied.

I. Background

This case was selected as a bellwether trial after the Court granted summary judgment in another Fosamax MDL case, Flemings v. Merck & Co., Inc. See In re Fosamax Prods. Liab. Litig., No. 06-MD-1789, 2009 WL 4042769 (S.D.N.Y. Nov. 23, 2009). The following facts are taken from the parties' Local Rule 56.1 Statements, the affidavits submitted in connection with the instant motion, and the exhibits attached thereto. Unless otherwise noted, the facts are undisputed.[1]

A. Fosamax

Defendant Merck is a New Jersey-based pharmaceutical company that makes and distributes the drug alendronate sodium under the brand name Fosamax. Fosamax is one of several drugs known as "bisphosphonates," and is taken orally. It was originally approved by the FDA for the treatment of post-menopausal osteoporosis and Paget's Disease in 1995, and the FDA has since approved additional uses. In June of 1999, Fosamax

[1] To the extent any sealed material is discussed in this opinion, the information is hereby unsealed in light of the strong presumption of public access.

was approved for the treatment of glucocorticoid-induced osteoporosis ("GiOP") in men and women. Glucocorticoids are a class of drugs that includes prednisone and other steroids used to treat rheumatoid arthritis.

Graves contends that Merck has long known of reports linking bisphosphonate use with the development of osteonecrosis of the jaw ("ONJ"). Graves alleges that Merck was aware that Fosamax could cause ONJ before Graves suffered her injuries, but failed adequately to warn the public of this risk. Graves references an article published in 2002, reporting that rats given Fosamax experienced delayed removal of necrotic bone, and various adverse event reports ("AERs") allegedly suggesting ONJ-related complications in certain persons being treated with Fosamax. To support her contention that the rat studies are relevant to the use in humans, Graves offers the deposition of Dr. Donald Kimmel, a Merck employee holding a D.D.S. and a Ph.D. who testified in his deposition that he had used rats to study bone growth in the study and writing of his Ph.D. dissertation, and that they can be "a good model of how bone behaves in many other species." (Kimmel Dep. Tr. at 16:1–22.)

With FDA approval, Merck modified its label in July 2005, informing the public that: "Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing, has been reported in patients taking

bisphosphonates." (Def. Rule 56.1 Statement ¶ 10.) Merck argues that the risk of bisphosphonate-associated ONJ was not known or reasonably knowable before it collected the information that led to the label change in 2005, and that even Graves' expert Dr. Robert Marx testified that while "he had treated Fosamax patients with ONJ as early as 2001 . . . even in 2003 he would not have alerted the medical community that Fosamax presented a risk of ONJ based on a few cases." (Def. Rule 56.1 Statement ¶ 12.)

B. Graves

Judith Graves is a 66-year-old Caucasian woman and a citizen of Florida. She alleges that she has suffered from ONJ and that her ONJ was caused by Fosamax. Graves has a history of severe rheumatoid arthritis, and to treat this condition, she has been prescribed various medications, including prednisone. In October 2001, Graves' general practitioner, Dr. Richard Adams, began to prescribe Fosamax to Graves, out of concern that her rheumatoid arthritis medications could cause her to lose bone density.

Merck contends that drugs Dr. Adams prescribed to Graves for her rheumatoid arthritis suppress the body's immune system and inhibit the ability of bones to heal, and while Graves disputes this characterization, her own expert, Dr. Adams, testified in his deposition that he was "aware . . . that each

of [these] medicines inhibited the body's ability to fight infection" and that "prednisone [has] an adverse effect on bone quality" when he prescribed Fosamax to Graves. (Adams Dep. Tr. at 56:16–57:20.)

In March of 2003, Graves had a tooth extracted, and subsequently suffered from exposed bone and infection in the extraction area that lasted for several months. This infection was diagnosed as osteomyelitis, but in November of 2004, Graves' oral surgeon Dr. John Akers, concerned that she may be suffering from ONJ relating to her Fosamax use, recommended that Graves cease taking Fosamax. Mrs. Graves had been taking Fosamax for at most three years and one month when Dr. Akers recommended the termination of her Fosamax treatment.

On August 4, 2005, while treating her, Dr. James Cherry, a maxillofacial and oral surgeon, formed a "working diagnosis" that Fosamax was contributing to Graves' condition.

Graves has also been treated by Dr. Douglas Villaret, a specialist in head and neck reconstructive surgery, who performed a radical resection of Graves' mandible in June of 2006 and a revision surgery in June of 2007. Dr. Villaret diagnosed Graves as having bisphosphonate-associated ONJ using a differential diagnosis. Dr. Villaret reasoned that the only three possible causes for Graves' injuries, as reflected in her medical records, were radiation therapy, severe trauma, and

bisphosphonate use. Given that there was no record of Graves having suffered from severe trauma or radiation therapy, he concluded that bisphosphonate use was the cause of Graves' injuries.

On August 8, 2007, Dr. Robert Marx began to treat Plaintiff after the fracture of a titanium plate placed in her jaw during Dr. Villaret's second resection surgery. At the time that Dr. Marx treated Graves, she was no longer suffering from ONJ, but Plaintiff characterizes Dr. Marx as having treated her for the "sequelae," or resulting injuries, of ONJ. Dr. Marx has testified that he concluded that Graves had suffered from ONJ related to her Fosamax use and based this conclusion on his review of prior doctors' treatment records. (Pl. Rule 56.1 Statement ¶¶ 30–33.)

Unlike many Fosamax patients that were prescribed Fosamax because they suffered from osteoporosis,[2] or osteopenia,[3] Dr. Adams prescribed Fosamax in order to prevent Graves from developing GiOP. The only bone scan presented in the record was taken in October 2002; the parties disagree about whether the result of that scan was 1.1 standard deviations above or below

[2] Osteoporosis is typically diagnosed when a patient has a bone density lower than 2.5 standard deviations below the mean for an average young adult.

[3] Osteopenia is typically diagnosed when a bone density between 1 and 2.5 standard deviations below the mean for an average young adult.

the young-adult mean, but it is clear that this bone scan was not taken until after Graves had been prescribed Fosamax for one year. (Pl. Rule 56.1 Statement ¶ 15; Def. SJ Reply Memo. at 4 n.4.)

II. Merck's Daubert Motion

The admission of expert testimony is governed by Federal Rule of Evidence 702, the three reliability-based requirements of which codified Daubert and its progeny. See In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 172 (S.D.N.Y. 2009) ("2009 Omnibus Daubert Opinion") (citing Fed. R. Evid. 702 Advisory Committee Note). Under Rule 702, the "district courts . . . act as gatekeepers by ensuring that expert scientific testimony both rests on a reliable foundation and is relevant to the task at hand." Id. (quoting Daubert v. Merrell Dow Pharms., 509 U.S. 579, 597 (1993)). The Court will therefore admit expert testimony only where it: (1) assists the jury to "understand the evidence or to determine a fact in issue"; (2) is offered by a qualified expert; and (3) satisfies the requirements of reliability outlined in Daubert. Fed. R. Evid. 702. In order for expert testimony to be admissible, it must satisfy all three of the above requirements, and the Court analyzes the qualifications of each of the proposed experts independently.

On July 27, 2009, the Court issued a 105-page opinion & order on the omnibus Daubert motions filed by Merck and the Plaintiff's Steering Committee ("PSC"). In that opinion, the Court summarized the factual background of the Fosamax MDL, discussing bisphosphonate drugs and their function, the FDA approval process for Fosamax, early reports of ONJ by bisphosphonate users, and Merck's reaction to these reports. See 2009 Omnibus Daubert Opinion at 172.

A. Dr. Marx

Although there was some dispute about the timing of Graves' injury in the parties' memoranda and at oral arguments, the inescapable conclusion is that the injury's onset was no later than March 31, 2003. The Court is following Graves' Plaintiff Profile Form in arriving at the March date, because twice in that form, she asserted that the "injury occurred 3/2003." (Graves PPF at 3.) Merck argues that Dr. Marx is not qualified to give testimony on the issue of specific causation where a plaintiff has been using Fosamax for less than three years, noting that "[i]n September 2009, this Court ruled that Dr. Marx's opinion that Fosamax could cause ONJ was 'not sufficiently reliable' to be admitted 'in cases involving less than three years of use.'" In re Fosamax Prods. Liab. Litig., No. 06-MD-1789, 2009 WL 2878439, at *5, 6 (S.D.N.Y. Sept. 9, 2009). Dr. Marx has opined in the past that Fosamax causes ONJ

when used for a period of time greater than three years, and the Court has deemed Dr. Marx's recent attempts to shorten this time-frame not sufficiently reliable to accept under Daubert.

Graves argues that the Court's prior ruling on this three-year use issue does not apply to Graves, who was taking glucocorticoids. According to Graves, Dr. Marx has maintained for several years that Fosamax can cause ONJ either in patients receiving Fosamax for at least three years or patients on Fosamax for purposes of GiOP treatment. In his textbook, Dr. Marx did distinguish the three-year usage risk factor from the use of glucocorticoids as a separate factor "increas[ing the] risk of developing [ONJ]," but three years' use of Fosamax is still described in that publication as a "threshold." Robert Marx, Oral & Intravenous Bisphosphonate-Induced Osteonecrosis of the Jaws: History, Etiology, Prevention, and Treatment 79–81 (Quintessence Books 2007). Additionally, Dr. Marx wrote that, among those patients "who have a confirmed diagnosis of bisphosphonate-induced osteonecrosis of the jaws" all "had a history of at least 3 years of oral bisphosphonate use and as many as 6 to 10 years in the most severe cases." Id. at 80. Therefore, Graves' current interpretation of Dr. Marx's earlier writing is contradicted by the facts cited in that publication. The Court's prior ruling that Dr. Marx is not qualified to give

expert testimony related to causation of ONJ in patients with less than three years' of Fosamax use stands.

B. Dr. Villaret

Merck proposes three reasons for excluding the expert testimony of Dr. Villaret regarding specific causation: (1) he was under a "mistaken impression that Plaintiff had used Fosamax for five years;" (2) Dr. Villaret "had not conducted a thorough case history of the previous condition and treatment of Plaintiff's jaw;" and (3) Dr. Villaret "cannot rule out other possible causes of Plaintiff's jaw injury." (Def. Daubert Memo. at 5–6.)

Dr. Villaret's originally mistaken impression about Graves' history of Fosamax use does not per se make his diagnosis of bisphosphonate-induced osteonecrosis of the mandible unreliable for purposes of Daubert. Dr. Villaret formed his opinion as to the cause of Graves' injury by differential diagnosis, which consisted of his determination that two of the three potential causes for the allegedly advanced osteonecrosis reflected in Graves' medical history--severe trauma causing avascularity and radiation--did not apply to Graves' case. Dr. Villaret concedes that he would not have assumed a patient who had taken Fosamax for less than three years would be likely to have Fosamax-induced ONJ, but states that, based on recent research, he

believes that his original diagnosis was nonetheless correct. (Decl. of Dr. Villaret ¶¶ 7–8.)

The factual questions about the thoroughness of Dr. Villaret's study of Graves' case history and the validity of his opinion that the extensive nature of Graves' observed injuries "rules out" certain other possible causes reflect on the weight a jury should afford Dr. Villaret's testimony and do not provide a proper basis for ruling that Dr. Villaret's testimony is unreliable under Daubert. In other words, Dr. Villaret's testimony is reliable because his testimony "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 152 (1999)

C. Dr. Cherry

Merck seeks to exclude the testimony of Dr. Cherry on the grounds that his testimony as to the specific causation issue is unqualified expert testimony, as he has not testified to a reasonable degree of medical certainty that Fosamax use caused Graves' condition.

Under Florida law, expert medical testimony is admissible where the expert testifies that his conclusions are satisfied by "the greater weight of the evidence;" or that his conclusion is "more likely than not" correct. Gooding v. Univ. Hosp. Bldg., Inc., 445 So. 2d 1015, 1018 (Fla. 1984). Dr. Cherry formulated

a "working diagnosis" that Graves had bisphosphonate-induced ONJ when he was treating Graves, and testified that his working diagnosis was "a little bit more causative than associative." (Cherry Dep. Tr. at 159:19–21.) In his deposition, Dr. Cherry was asked the following question: "You didn't actually ever--you would agree with me that you didn't have sufficient evidence to be able to conclude that bisphosphonates were in fact the cause of her problems, did you?" Dr. Cherry then gave a one-word answer: "No." (Id. at 161:5–11.) The most grammatical reading of the above question-and-answer pair is that Dr. Cherry was contradicting the questioner's assertion that he lacked "sufficient evidence to be able to conclude" that Fosamax caused Graves' injuries in this case. In other words, Dr. Cherry disagreed with the premise that he could not diagnose bisphosphonate-related ONJ with the evidence before him. The answer given above may be ambiguous because of the double-negatives involved, but it is not ipso facto unreliable. Dr. Cherry's testimony satisfies the "more likely than not" standard and is therefore admissible under Florida law.

D. Dr. Akers

Dr. Akers recommended that Graves cease taking Fosamax in November 2004, and although he asked her to return in a week, he revealed in his deposition that she did not return to his care after he made this recommendation. (Akers Dep. Tr. at 44:3-6.)

When asked about the certainty of his recommendation that Graves cease taking Fosamax, Dr. Akers testified in his deposition: "I don't think I concluded anything other than the fact that she was on Fosamax and prednisone and she had exposed bone for a long period of time." (Id. at 44:14–20.) Furthermore, although he thought that Graves' condition could be ONJ, he was unaware of her prior dental history and the duration of her Fosamax use. Id. at 45:6-13. On these facts, Dr. Aker's testimony is mere speculation, and because his testimony does not satisfy even the "more likely than not" standard required under Florid law, the Court holds that it is not admissible.

E. Dr. Adams

Graves does not oppose Merck's motion to exclude Dr. Adams' testimony on specific causation, and the motion is therefore granted.

III. Merck's Motion for Summary Judgment

The parties agree that this court, sitting in diversity, should apply Florida tort law on this motion for summary judgment. Graves alleges that she developed ONJ as a result of her use of Fosamax. Specifically, Graves' claims are premised on strict products liability (under theories of failure to warn and design defect) and negligence. Graves has withdrawn her express and implied warranty claims.

Merck moves for summary judgment:

(1) as to all claims, because there is insufficient admissible evidence from which a jury could conclude that Fosamax specifically caused Graves' injuries;

(2) as to the failure to warn claim, because Fosamax did not present a known or reasonably knowable risk of ONJ before March of 2003;

(3) as to the failure to warn claim, because Graves has presented no evidence that a warning about ONJ would have changed Dr. Adams' decision to prescribe Fosamax to her; and

(4) as to the design defect claim, because Dr. Smith prescribed Fosamax for an "off-label" use in Mrs. Graves' case.

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). Therefore, "disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Additionally, Merck, as the movant "bears the burden of demonstrating that summary judgment is appropriate." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

For the following reasons, Merck has not met this burden, and therefore, the motion for summary judgment is denied.

A. Expert Testimony on Specific Causation

As Drs. Villaret and Akers have provided admissible expert opinion that Graves' injury was proximately caused by her Fosamax use, Plaintiffs have put forth sufficient evidence to create a genuine issue of material fact on the issue of specific causation. Merck's motion for summary judgment on this ground is denied.

B. Failure to Warn

Under Florida law, a manufacturer of a product has a duty to warn of all non-apparent "scientifically discoverable dangers," even if that manufacturer does not have "actual knowledge" of a particular danger. Carter v. Brown & Williamson Tobacco Corp., 778 So. 2d 932, 942-943 (Fla. 2000). Once a manufacturer has a duty to warn, "[s]trict liability and negligent failure to warn cases boil down to three elements that Plaintiff must prove: 1) that the warnings accompanying the item were inadequate; 2) that the inadequacy of the warnings proximately caused Plaintiff's injury; and 3) that Plaintiff in fact suffered an injury by using the product." Colville v. Pharmacia & Upjohn Company LLC, 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008) (citations omitted).

Merck seeks summary judgment on Graves' failure to warn claims arguing that these claims fail because: (1) Merck did not have a duty to warn of the potential for ONJ at the time Graves was injured; and (2) Graves has not introduced sufficient evidence to demonstrate that an earlier warning would have prevented Dr. Adams from prescribing Fosamax, and therefore Graves has not proven proximate causation.

1. Knowable Risk of ONJ

Merck argues that it had no duty to warn Graves of the danger of Fosamax before March 2003, the time at which Graves claimed she suffered both physical and psychological injuries "as a result of Fosamax use" in her Plaintiff Profile Form. (Graves PPF at 3.) In argument and briefing on this summary judgment motion, Graves argues that Merck had a duty to warn that continued until November 2004, and has attempted to argue that Graves' proper injury date is November 2004. The sole evidence given in support of this later injury date is that a firm diagnosis was not made until November 2004. However, in her Rule 56.1 Statement, Graves concedes that she suffered from exposed bone and infection in the months following her March 2003 tooth extraction but argues that this infection was the result of the presence of necrotic bone. Given the statement in her Plaintiff Profile Form and the attempt to attribute her post-March 2003 infection to the presence of necrotic bone at

that point, the Court recognizes March 2003 as Graves' injury date for purposes of this litigation.

Merck argues that new evidence, "uncovered" during the Boles II trial, demonstrates that Merck had no duty to warn before March of 2003. While the Court has previously ruled that a plaintiff alleging a 2003 date of first ONJ injury created a triable issue of fact, Merck notes that the Court did so because Dr. Suzanne Parisian "testified in the 2009 Daubert hearing that by 1999 Merck should have included reports of exostosis in the Adverse Reaction section of the Fosamax label. However, more recent testimony by Dr. Parisian and Dr. Marx allegedly demonstrates that Merck did not have a duty to warn in or before 2003." (Def. SJ Memo. at 7-8.) Specifically, Merck argues that Dr. Parisian "admitted that because she is not a dentist she is not qualified to state whether dentists frequently see exostosis," and that "exostosis occurs commonly in the human mouth." (Id. at 8.)

Furthermore, Merck seeks to show that there was no duty to warn prior to 2003 by introducing Dr. Marx' Boles II testimony, in which he stated that he refrained from sending out alerts about the potential for bone death complications connected to Fosamax use to the buyers or readers of his book because he was not "going to go sending out alerts based on just theory, based on a few cases." (Boles II June 9, 2010 Trial Tr. at 275.)

Graves disputes Merck's argument that there was no known risk at the time of injury by arguing that Merck was on notice of the risk for bisphosphonate-related ONJ before 2003. Graves contends that testimony by Dr. Parisian and Dr. Thomas Bold, Senior Director of Clinical Risk Management & Safety Surveillance at Merck, indicates that "a single report [of an adverse reaction] can constitute a safety signal." (Bold Dep. at 19:9-21:2.) Graves cites the Court's opinion that "[a] full reading of Dr. Parisian's report, her testimony at her deposition, and her testimony at the Daubert hearing reveals that she believes Merck's duty to warn was clear by October 2003 and may have existed as early as the mid - to late - 1990's." In Re Fosamax Prods. Liab. Litig., 647 F. Supp. 2d 265, 275 (S.D.N.Y. 2009). Graves refers to various adverse event reports and rat studies which indicate that Merck should reasonably have known--even if it did not actually know--that bisphosphonates like Fosamax can cause ONJ. Additionally, Graves cites Dr. Kimmel's testimony to argue that the most likely mechanism underlying bisphosphonates and ONJ was known to Merck prior to 2003, as Dr. Kimmel testified that bisphosphonate acts as a "resorption inhibitor." (Kimmel Dep. Tr. at 95:3-9.) As Merck knew that Fosamax suppressed bone resorption, and that the jaw bone is more sensitive to bisphosphonate uptake, there is some

evidence to suggest that Merck could have known Fosamax would lead to ONJ after extended use by humans.

The testimony of Dr. Parisian to which Merck alludes does not "vitiate" her prior testimony about the significance of exostosis reports, because the reports themselves reflect that the dentists did not consider the occurrence of exostosis to be common. Merck's attempted use of Dr. Marx's testimony that he would not personally have issued a warning about the possibility of ONJ is also unpersuasive, given that Merck's legal duty is defined by Florida tort law and is not a similar duty to one owed Dr. Marx.

There are issues of material fact about when Merck had a duty to warn patients of the risk of ONJ, and therefore summary judgment is not appropriate with respect to the timing of Merck's duty to warn.

2. Dr. Adams' Decision to Prescribe Fosamax

To establish proximate causation in a failure to warn claim resulting from a pharmaceutical product, a plaintiff must show that an appropriate warning would have affected the course of treatment of the plaintiff's physician. In re Fosamax Prods. Liab. Litig., No. 06-MD-1789, 2010 WL 1257299, at *5 (S.D.N.Y. March 26, 2010). Merck contends that Graves has not offered sufficient evidence to establish proximate causation of her failure to warn claim, and that had Merck warned of the risk of

ONJ before March 2003, Dr. Adams would not have changed his prescription of Fosamax to Graves. In support of this contention, Merck notes that Dr. Adams continues to prescribe Fosamax to some patients, and argues that Dr. Adams' prescription was "off-label" or "not indicated," and therefore Dr. Adams would not have paid attention to Merck's warning.

Even assuming arguendo that Graves' use of Fosamax was "off-label," it does not necessarily follow that all warnings will be ignored merely because a doctor decided that some potential risks are outweighed by the benefits of a drug. Likewise, Dr. Adams' continued prescription of Fosamax to some patients does not prove that he would not have changed his decision to prescribe Fosamax. Dr. Adams's deposition clearly reflects that much of the information revealed after July 2005 has changed his prescription process, and that he would have considered Graves' situation very differently when he placed her on Fosamax if he had possessed all of the currently available information at the time. (See Adams Dep. Tr. at 10:15-17 ("Q. Do you prescribe Fosamax today for patients who are taking corticosteroids . . . ? A. No.").) Therefore, as there is a factual dispute, summary judgment is not warranted on the issue of whether Dr. Adams would have changed his prescription of Fosamax to Graves.

C. Design Defect

To state a claim for a design defect--whether on a theory of negligence or of strict liability--a plaintiff must show that a product is "unreasonably dangerous." In re Fosamax Prods. Liab. Litig., No. 06-MD-1789, 2010 WL 1257299, *6 (S.D.N.Y. Mar. 26, 2010). Determining whether a product is "unreasonably dangerous" requires a balancing of:

> the likelihood and gravity of potential injury against the utility of the product, the availability of other, safer products to meet the same need, the obviousness of the danger, public knowledge and expectation of the danger, the adequacy of instructions and warnings on safe use, and the ability to eliminate or minimize the danger without seriously impairing the product or making it unduly expensive.

Radiation Technology, Inc. v. Ware Const. Co., 445 So. 2d. 329, 331 (Fla. 1983). Merck claims that it is entitled to summary judgment on Graves' design defect claim because Fosamax was prescribed for a non-indicated or "off-label" use in Graves' case, and a patient may not bring a design defect claim when that patient did not use the drug as designed by the manufacturer.

1. Dr. Adam's Prescription

Merck's motion for summary judgment with respect to Graves' design defect claim depends on there being no issue of material fact about whether Dr. Adams prescribed Fosamax to Graves for a properly indicated use. Merck contends that Fosamax was only

appropriate for treatment of glucocorticoid-induced osteoporosis (the deterioration of bone density due to the use of certain immunosuppressant steroids, such as prednisone, which Mrs. Graves was taking) where the prescription from glucocorticoids was higher than 7.5 mg/day, and that Graves does not fall into this category of usage. (Def. SJ Memo. at 3-4, 11-12.) By contrast, Graves argues that she does fall into the GiOP treatment indication and that the more general indication for "prevention of osteoporosis" applies to Graves' prescription. As there is a factual dispute about whether or not Graves was prescribed Fosamax for an indicated use, summary judgment on this issue is inappropriate.

2. Florida Products Liability Law for Off-Label Prescriptions

Merck incorrectly argues that Graves has conceded that her design defect claim fails as a matter of law if she was not a patient for whom Fosamax was indicated; Graves made no such concession and resisted this characterization at oral argument. Rather than citing case law affirmatively supporting its contention, Merck argues that it "is unaware of any authority, let alone Florida authority, holding that a prescription medication manufacturer can be held liable for design defect under the risk/benefit test where the plaintiff was not a patient for whom the medication was designed." (Def. SJ Memo. at

11.) This contention assumes, without making any clear factual assertion, that Fosamax was designed only for FDA-approved purposes, and a per se rule would imply that drug companies never have in mind off-label sales of drugs when designing a drug. The only relevant Florida case law of which the Court is aware defines a manufacturer's duty to prevent harm broadly, as extending to any "reasonably foreseeable injuries" resulting from the use of a product. Lewis v. City of Tallahassee, 2006 WL 231291, *2 (N.D. Fla. Jan. 30, 2006) (citing Tampa Drug Company v. Wait, 103 So. 2d 603, 607 (Fla. 1958)). Therefore, the Court is not prepared to rule as a matter of law that one prescribed a drug for an "off-label" use can never bring a design defect claim, and Merck's motion for summary judgment is denied on these grounds.

IV. Conclusion

As discussed above, there are genuine and material issues of fact in this case, and therefore Merck's motion for summary judgment is DENIED.

Additionally, for the reasons described above, Merck's motion to exclude unqualified expert testimony under Daubert GRANTED with respect to Drs. Adams, Akers, and Marx, and is DENIED with respect to Drs. Villaret and Cherry.

SO ORDERED.

Dated: New York, New York
October 22, 2010

John F. Keenan

JOHN F. KEENAN
United States District Judge